STATE MEDICAID DUR BOARD MEETING

THURSDAY, June 10, 2010
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:
Mark Balk, PharmD.
Kathy Goodfellow, R.Ph.
Peter Knudson, D.D.S.
Joseph Miner, M.D.
Joseph Yau, M.D.
Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Wilhelm Lehmann, M.D.
Bradley Pace, PAC

Board Members Excused:
Dominic DeRose, R.Ph.
Cris Cowley, M.D.
Brad Hare, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Other Individuals Present:

Meeting conducted by: Wilhelm Lehmann, M.D.

1 Review and Approval of Minutes: Mark Balk moved to approve the minutes. Neal Catalano seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Mark Balk, Dr. Yau, Dr. Lehmann, Tony Dalpiaz, Neal Catalano, Dr. Miner, and Brad Pace.

2 P&T Committee Report: Tim Morley addressed the Board and announced Duane Parke's retirement. Right now the entire pharmacy team is covering Duane's responsibilities while a replacement is hired and trained.

3 Election of a New Chair: Dr. Knudson nominated Dr. Lehmann. Dr. Miner seconded the nomination. There were no other nominations.

Dr. Miner moved to elect Dr. Lehmann by acclimation. Mark Balk seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Mark Balk, Dr. Yau, Tony Dalpiaz, Neal Catalano, Dr. Miner, and Brad Pace.

4 Samsca: Dr. CarrieAnn McBeth of the University of Utah College of Pharmacy addressed the Board and presented a report and recommendations prepared on Samsca.

Proposed Prior Authorization criteria presented were:

- Documentation that tolvaptan was initiated in the hospital.
- Documentation that tolvaptan is required for hypervolemic or euvolemic hyponatremia, and not for hypovolemic hyponatremia or heart failure.
- Documentation that hyponatremia is symptomatic if serum sodium > 125 mEq/L.
- Documentation of failure of other treatment strategies, including fluid restriction. Failure of salt administration should only be required for euvolemic hyponatremia. Failure of demeclocycline should be required for SIADH. Evidence should be required that the underlying disease state causing the hyponatremia is being adequately treated.
- Restrict the dose of tolvaptan to 60mg daily.

The DUR Board asked the cost of the medication. The cost is $300 per tablet for all strengths.

The Board proposed adding a fail-first requirement for demeclocycline.

Dr. Yau asked how long treatment on Samsca is supposed to last. None of the trials were longer than 60 days, so the Board proposed making the duration of treatment for 60 days.

Rick Sorenson stated that the PA form needs to be very specific and clear so that the PA does not get held up for lack of information when a person is waiting to be discharged.

The Board was concerned about disrupting therapy for a patient that was stabilized on a medication with an overly restrictive PA. Lisa stated that Medicaid may approve a small quantity of a medication until the next DUR Board meeting and then bring it before the Board for an exception to policy.

Tim was concerned that perhaps leaving patients on this medication off criteria would create safety risks. This medication has some significant safety concerns. Jennifer asked Dr. McBeth if there was a restricted distribution channel for this medication, but she did not know.

Dr. Lehmann stated that years ago low molecular weight heparins were a big deal, and that discharge planning used to include getting people prior authorized for the medication. He did not think that this drug would be prescribed by anyone but a specialist who is skilled in treating electrolyte imbalances, and who would be comfortable with requesting the PA.

Mark Balk moved to accept the criteria as amended, and re-examine whether or not the PA had created access to care issues in nine months when the Board has to re-hear the PA. Dr. Miner seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Mark Balk, Dr. Yau, Dr. Lehmann, Tony Dalpiaz, Neal Catalano, Dr. Miner, and Brad Pace.

5 Multaq: Dr. Bryan Larson from the University of Utah College of Pharmacy addressed

the Board and presented research on Multaq.

Dr. Lehmann asked in what way Multaq was safer than Amiodarone. Thyroid toxicity, neurological, and pulmonary adverse events are the main issues seen with amiodarone that are not seen with Multaq. This is believed to be due to the iodine in the lipophilic side chain of amiodarone. There is also a lower discontinuation rate with Multaq.

Mark asked if Dr. Larson if he could quantify the benefits and risks in absolute numbers. For every 1,000 patients treated with Multaq instead of amiodarone, there would be 228 patients with a recurrence of atrial fibrillation at one year, but there would be 9.2 fewer deaths and 62 fewer adverse events requiring discontinuation of the drug.

Dr. Lehmann asked for a summary of recommendation. Dr. Larson recommended a PA requiring a trial of amiodarone, and ruling out the contraindications.

Mark asked if there should be a time frame for having tried amiodarone, since that drug has been around for a very long time. The Board did not think that there should be a time frame for this. Dr. Larson did state that the efficacy of both agents tends to wane over time

Dr. Knudson asked if there is a surgical procedure for this condition. Dr. Larson stated that there is, but it is not always appropriate.

Dr. Dennis Jacobson from Sanofi Aventis addressed the Board in favor of Multaq. Ethical marketing strategies for the drug were highlighted.

The Board discussed the proposed PA criteria. A fail-first on any generic, since there are safer generics available, was discussed. National guidelines place amiodarone very low on the list. Mark Balk disclosed that he works for Sanofi-Aventis in oncology. He stated that the anti-arrhythmic class is diverse and there are some agents in the class (e.g. Tikosyn) that require in hospital initiation. He suggested that the class be reviewed as a whole and the guidelines with other medications be reviewed.

Dr. Miner moved to review the entire class and not PA Multaq based on today's discussion. Neal seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Dr. Yau, Dr. Lehmann, Tony Dalpiaz, Neal Catalano, Dr. Miner, and Brad Pace. Mark Balk recused himself.

6 Suboxone: Dr. Lehmann stated that only housekeeping will be discussed to decrease the administrative burden on the Suboxone PA. No public comment will be accepted due to lack of time at this meeting.

Lisa Hulbert reviewed the workload being created by Suboxone PA's. The current PA guidelines were distributed. Tim recently attended a national conference at which Suboxone was discussed. The presentation can be summarized in four points:

- There is no reason for doses greater than 24mg/day
- There are three classes of patients: 30% in denial, 40% say they have a

problem but are not ready to address it, 30% are ready for action and will need a counseling component with the medication. Only those last 30% should be given Suboxone.

- Prescribers should insist on pristine urine screens.
- Therapy should last at least 18 months.

Lisa asked the Board to change the PA to a one-step PA that will approve 18 months. The thing that Medicaid will lose is the clean urine screens. However, the PA requires evidence that this will be required.

Dr. Miner stated that he likes the idea of the 18-month approval. He stated that the prescribers should be insisting on clean urine screens. Lisa gave the example of the patient that was addressed at the last petition meeting that had deceived the prescriber of Suboxone.

The PA nurses described how they enforce the requirements for counseling and medication monitoring while on Suboxone.

The DUR Board asked how the concomitant use of opioids would be handled. Jennifer stated that computer edits are not allowing this any longer. This would still leave the possibility open for going on and off the wagon several times, but at least prevent opioids and Suboxone from being within the same 30 day period.

Dr. Miner moved to authorize an 18-month treatment with Suboxone at a maximum of 24mg per day added to the existing criteria. The PA nurses asked what would happen at the end of 18 months. Dr. Miner stated that the client would need to re-apply for the PA with a clean urine screen at the end of that time, but that it may be appropriate to leave them on it for years as is done with Methadone patients. Tony Dalpiaz seconded the motion. The motion was approved unanimously by Kathy Goodfellow, Dr. Knudson, Mark Balk, Dr. Yau, Dr. Lehmann, Tony Dalpiaz, Neal Catalano, Dr. Miner, and Brad Pace.

The next DUR Board meeting was scheduled for Thursday May 13, 2010.

The DUR Board Prior Approval Subcommittee to considered 2 petitions this month. 1 was approved.

Minutes prepared by Jennifer Zeleny